



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

December 14, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Rory Mahony
General Manager/COO
Nature's Way Products, Inc.
1375 N. Mountain Springs Pkwy.
Springville, UT 84663

Ref. #: DEN-05-04

Dear Mr. Mahony:

Consumer Safety Officer Ricki Chase-Off visited your manufacturing facility on August 30, 2004. During that inspection, a sample of Nature's Way Brand Korean Ginseng Root capsules, 510 mg, lot #341524, was collected. Our analysis of these capsules found the pesticide chemical quintozone. The Report of Sample Analysis is attached for your information.

This article is adulterated within the meaning of 21 U.S.C. 342(a)(2)(B) while held for sale after shipment in interstate commerce in that it bears and contains a pesticide chemical, namely, quintozone, which is unsafe within the meaning of 21 U.S.C. 346a since no tolerance or exemption from tolerance has been granted for the use of such pesticide chemical on ginseng.

As a manufacturer of food within the meaning of 21 U.S.C. 321(ff), you are responsible for assuring that the products you distribute are not adulterated and are otherwise in compliance with the law. Failure to do so may result in regulatory action, without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps you have taken to correct these violations and preclude their recurrence. Your response should include details regarding your intent with respect to this specific lot of Nature's Way Brand Korean Ginseng Root Capsules, including product already distributed. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Page 2 – Nature's Way Products, Inc. Warning Letter
December 14, 2004

Your response should be sent to Ms. Shelly L. Maifarth, Compliance Officer, Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087. She may be reached at (303) 236-3046 if you have any questions about this matter.

Sincerely,

Howard L. Maness, ADD for

B. Belinda Collins
District Director

Enclosure:
Report of Sample Analysis